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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,837	02/13/2007	Chikao Morimoto	2144.0150002/RWE/RAS	8525

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EXAMINER	
CHONG, KIMBERLY	
ART UNIT	PAPER NUMBER
1635	
MAIL DATE	DELIVERY MODE
12/24/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/584,837	MORIMOTO ET AL.	
	Examiner	Art Unit	
	KIMBERLY CHONG	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *5,13-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 6-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 June 2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/11/07, 3/31/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I claims 2-12 in the reply filed on 03/31/2008 is acknowledged.

Status of the Application

Claims 1-35 are pending. Claims 1-4 and 612 are currently under examination. Claims 5, 13-35 and non-elected subject matter are withdrawn as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, and 6-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

To satisfy the written description requirement, MPEP §2163 states, in part "…a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had

possession of the claimed invention." Moreover, the written description requirement for a genus may be satisfied through sufficient description of a representative number of species by "…disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between functional and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus."
The claims are drawn to a method of identifying a substance that down-regulates an immune response comprising determining whether the substance inhibits an interaction between factors in the CD26 signaling pathway, comprising determining whether the substance inhibits the interaction between CD26 and caveolin-1, wherein the interaction is protein-protein binding, wherein the interactions are measured as recited in claim 4, wherein the method comprises contacting cells or extracts, wherein the cells are T-cells or monocytes, wherein the cells comprise a vector, wherein said substance is part of a library of substances and drawn to a kit for identifying said substance.

The instant method embrace and contemplate determining whether any substance is capable of inhibiting any interaction between factors, known or yet to be discovered, that are involved in any upstream or downstream CD26 signaling pathway, . The instant specification describes one potential CD26 signaling pathway and discloses the use of siRNA to inhibit specific interactions of factors in this pathway however this descriptions does not adequately provide written description for the breath of the instant claims.

The specification as filed does not provide specific guidance that would lead one of skill in the art to the claimed invention and the prior art cannot provide the specific guidance as demonstrated by Meester et al. (Immunology Today 1999, vol. 20(8): 367-375) which teach CD26 is involved in numerous cell signaling processes (see entire article). The specification does not describe the infinite number of factors involved in the CD26 signaling pathway such to constitute a description of the entire genus claimed.

MPEP §2163 states, in part "A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process." Moreover, MPEP §2163 states, in part: "[A] patentee of a biotechnological invention cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the results obtained from species other than those specifically enumerated. A patentee will not be deemed to have invented species sufficient to constitute the genus by virtue of having disclosed a single species when … the evidence indicates ordinary artisans could not predict the operability in the invention of any species other than the one disclosed. *In re Curtis*, 354 F.3d 1347, 1358, 69 USPQ2d 1274, 1282 (Fed. Cir. 2004).

Therefore, Applicants have not adequately described the invention. Applicants are reminded that the written description requirement is separate and distinct from the enablement requirement. *In re Barker*, 559 F.2d 588, 194 USPQ

470 (CCPA 1977), cert. denied, 434 U.S. 1064 (1978); *Vas-Cath, Inc.* v. *Mahurkar*, 935 F.2d 1555, 1562, 19 USPQ2d 1111, 1115 (Fed. Cir.1991).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 3, 4, 6, 7 and 8 are rejected under 35 U.S.C. 102(a) as being anticipated by Williams et al. (Clin Exp Immunol January 2003).

The claims are drawn to a method of identifying a substance that down-regulates an immune response comprising determining whether the substance inhibits an interaction between factors in the CD26 signaling pathway, comprising determining whether the substance inhibits the interaction between CD26 and caveolin-1, wherein the interaction is protein-protein binding, wherein the interactions are measured as recited in claim 4, wherein the method comprises contacting cells or extracts, wherein the cells are T-cells or monocytes, wherein the cells comprise a vector, wherein said substance is part of a library of substances and drawn to a kit for identifying said substance.

For purposes of prior art, the following terms in claim 1 are given their broadest reasonable interpretation: The term *interaction* is not defined in the

instant specification and therefore any association, binding or cellular function between factors such as phosphorylation of a factor which would lead to activation of a downstream substance would meet the limitations of this term. The “CD26 signaling pathway" is not defined in the instant specification and is very broad given CD26 can be involved in many upstream or downstream signaling process in cells so for purposes of prior art, substances that are involved in any process of CD26 or are associated with any upstream or downstream activation or inactivation of CD26 would meet this limitation. The specification in Figure 9 shows a model of a CD26 signaling pathway but specification does not disclose the claims are limited to only the factors shown in the model. Further, any prior art that comprises determining whether a substance can inhibit an interaction between factors in the CD26 signaling pathway would meet the limitations of claim 1. The following rejection(s) are based on the above interpretations.

Williams et al. teach CD26 is involved in T cell stimulation and associates with CD45 tyrosine phosphatase. Williams et al. teach CD45 is a necessary factor in the CD26 signal transduction (see page 70). Williams et al. teach DC26 and CD45 are found associated in human T cells as demonstrated by immunoprecipitation (see page 69). Williams et al. teach a CD26 inhibitor, TMC-2, was able to inhibit the interaction of CD45 with CD26 and therefore down-regulate T cell response (see pages 72-74).

Thus, Williams et al. anticipates 1, 3, 4, 6, 7 and 8 of the instant invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3-4, 6-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams et al. (Clin Exp Immunol January 2003) and Pei et al. (US Patent No. 7, 205,409)).

The claims are drawn to a method of identifying a substance that down-regulates an immune response comprising determining whether the substance inhibits an interaction between factors in the CD26 signaling pathway, comprising determining whether the substance inhibits the interaction between CD26 and caveolin-1, wherein the interaction is protein-protein binding, wherein the interactions are measured as recited in claim 4, wherein the method comprises contacting cells or extracts, wherein the cells are T-cells or monocytes, wherein the cells comprise a vector, wherein said substance is part of a library of substances and drawn to a kit for identifying said substance.

For purposes of prior art, the following terms in claim 1 are given their broadest reasonable interpretation: The term *interaction* is not defined in the instant specification and therefore any association, binding or cellular function between factors such as phosphorylation of a factor which would lead to

activation of a downstream substance would meet the limitations of this term. The “CD26 signaling pathway" is not defined in the instant specification and is very broad given CD26 can be involved in many upstream or downstream signaling process in cells so for purposes of prior art, substances that are involved in any process of CD26 or are associated with any upstream or downstream activation or inactivation of CD26 would meet this limitation. The specification in Figure 9 shows a model of a CD26 signaling pathway but specification does not disclose the claims are limited to only the factors shown in the model. Further, any prior art that comprises determining whether a substance can inhibit an interaction between factors in the CD26 signaling pathway would meet the limitations of claim 1. The following rejection(s) are based on the above interpretations.

Williams et al. is relied upon as above. Williams et al. do not teach libraries if CD26 inhibitors.

Pei et al. teach method of generating CD26/DDP IV inhibitors and teach said inhibitors are useful in inhibiting CD26/DDP IV in the treatment of various immunomodulatory diseases. Pei et al. teach generation of libraries of inhibitors of CD26/DDP IV and teach identifying compounds capable of inhibiting the activity of CD26/DDP IV (see for example columns 45-49).

It would have been obvious to use the methods of Pei et al. to identify compounds that are capable of interacting with the factors in the CD26 pathway. It would have further been obvious to generate a kit for identifying a substance that inhibits the interaction of factors in the CD26 pathway. One of ordinary skill

in the art at the time the invention was made would want identify inhibitors of factors in CD26 and would have expected success given Williams et al. teach identification of an inhibitor of specific factors in the CD26 signaling and teach such inhibitors provide therapeutic effects on disease such as rheumatoid arthritis. Further, one of ordinary skill in the art would clearly want to provide kits for identifying said substances in efforts to screen libraries of compounds for potential inhibitors that are capable of modulating the immune response involved in diseases due to factors in the CD26 signal transduction pathway.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Friday between 7-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached at 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants

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/Kimberly Chong/
Examiner
Art Unit 1635